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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/552,969	04/20/00	DAX S	ORT-1230

HM12/0922

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EXAMINER	
LIU,H	
ART UNIT	**PAPER NUMBER**
1624	4

DATE MAILED: 09/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/552,969	Dax et al.
Examiner	**Group Art Unit**
Hong Liu	1624

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-22* is/are pending in the applicat

Of the above, claim(s) *15-18* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14 and 19-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-14 and 19-22, drawn to a compound of formula A, a pharmaceutical composition and a method of use, classified in class 546, subclass 190, 200.

   II. Claims 15-18, drawn to a compound, classified in class 548, subclass 427.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-VI are directed to structurally dissimilar compounds such that the variable positions of the substituent on hetero ring created by varying the definitions of the formula do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention would not render obvious the others, for example, N-substituted tricyclic rings are different from carbon substituted rings. Thus, separate searches in the literature as well as in the U.S. Patent Clarification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious.

During a telephone conversation with Mr. John Harbour on 09/08/2000 a provisional election was made with traverse to prosecute the invention of Group I, claim 1-14 and 19-22.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application, 60/132,660, upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-22 of this application. The provisional application does not disclose the sulfonamido substituents are at the 2-position of the benzoindole ring. Rather, the sulfonamido substituents are N-substituted to the benzoindole ring.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

No sufficient testing data is provided for any of the compounds listed in the specification. Examples should be of sufficient scope as to justify the scope of the claim. However, the generic claims are much broader in scope than is represented by the testing. The definitions of the various R variables on the tricyclic ring system embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the "working examples' fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See In re Fouch, 169 USPQ 429.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provide by the specification. See In re Surrey 151 USPQ 724 regarding

sufficiency of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability" have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

Claims 20-22 are drawn to a method of treating disorders associated with NPY receptor subtype Y5. This claims are interpreted to include any and all disorders associated with this particular mode of action. The specification reads on any and all eating disorders, obesity, depression, anxiety, migraine, pain, etc. However, the applicant discloses on P.4 of specification that "compounds that mimic NPY are postulated to be useful for the treatment of anxiolytic disorders." See In re Surrey, 252 USPQ 724, regarding sufficiency of disclosure. Competent evidence of art-recognized efficacy for intended uses needs to be provided. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the likelihood of in vivo use for all uses being claimed. See Ex parte Powers, 220 USPQ 925.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

6. 1). Claim 2 recites the limitation "alkyl," "alkoxy," "alkylene," "aryl" etc. . There is insufficient antecedent basis for this limitation in the claim. Note, in claim 1, the corresponding variables are defined as "C1-8alkyl," "C1-8alkoxy," "naphthyl," etc.

2). Claim 19 recites the limitation "alkyl," "alkoxy," "alkylene," "aryl" etc. . There is insufficient antecedent basis for this limitation in the claim. Note, in claim 1, the corresponding variables are defined as "C1-8alkyl," "C1-8alkoxy," "naphthyl," etc.

7. 3). Claims 19 appears to be a substantial duplicate of Claim 2.

8. 4). Claims 20 and 21 are of indeterminate scope for more than one reason. First, no one particular disorder is recited. Second, the claim language may read on diseases not yet fully understood to be affected by NPY Y5 receptor antagonists. In addition, how does one determine who is "in need of such treatment" and who is not. Specification appears to give no guidance to the answer.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-14 and 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by McNally et al. (Bioorg. Med. Chem. Lett., 2000). McNally teaches the compounds, compositions and methods of use of the instant invention..

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

H.L
Hong Liu
September 18, 2000

Mukund J. Shah

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624